UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804
THIS DOCUMENT RELATES TO:	Case No. 17-md-2804
County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al., Case No. 18-op-45090 (N.D. Ohio)	Judge Dan Aaron Polster
The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al., Case No. 17-op-45004 (N.D. Ohio)	
"Track One-B Cases"	

OPPOSITION TO THE PHARMACY DEFENDANTS' MOTION FOR RECONSIDERATION OF THE COURT'S DECEMBER 10, 2019 ORDER

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INTRODUCTION

On December 10, 2019, the Court ordered the Pharmacy Defendants to "produce transactional dispensing data for the entire United States from 1996 forward." ECF No. 2976 at 2.[1] As the Court noted, this production is "essentially identical to the scope of discovery that was obtained from the Distributor Defendants in Track One." *Id*. The Court permitted the Pharmacy Defendants to stage the production – "first produc[ing] Ohio data, then nearby regional data, including West Virginia and Kentucky; and then roll[ing] out data for the rest of the country" – or, if "less expensive or quicker," they could "simply produce all regional or national data at once." *Id.*

On December 20, 2019, the Pharmacy Defendants[2] moved the Court to reconsider its order. ECF No. 3029 ("Defs' Br."). The motion asserts three grounds for reconsideration, each of which was previously raised and/or litigated in this action, and ruled upon by the Court or Special Master Cohen.

First, the Pharmacy Defendants contend the Court's order disregards "individual interests in medical privacy" as required by Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). This contention ignores Case Management Order No. 2 (ECF No. 441, "CMO 2"), the protective order entered by the Court, which includes a section addressing HIPAA-Protected Information. CMO 2 at 32. It also ignores the multiple other orders in this MDL addressing HIPAA-governed information, up to and including the December 13, 2019 "Protective Order Regarding Disclosure by Plaintiffs of Confidential Medical Records" (ECF No. 2987).

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[1] Citations, internal quotations and footnotes omitted and emphasis added unless noted otherwise.

[2] "Pharmacy Defendants" are CVS Rx Services, Inc., CVS Indiana, L.L.C., CVS Pharmacy, Inc., and Ohio CVS Stores, L.L.C. ("CVS"), Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Support Center, Rite Aid of Ohio, Inc., and Rite Aid Hdqtrs. Corp. ("Rite Aid"), Walgreen Co. and Walgreen Eastern Co. ("Walgreens"), HBC Service Company, an unincorporated operating division of Giant Eagle, Inc. ("Giant Eagle"), Discount Drug Mart ("DDM"), and Walmart Inc. ("Walmart").

The Pharmacy Defendants implicitly acknowledge that CMO 2 addresses their data privacy concerns, but assert that the "massive assemblage of data is at risk of public disclosure." Defs' Br. at 8. Some risk is not unique to this case or this production; indeed, it is no different than with the de-anonymized claims data, which Defendants pressed for, and which plaintiffs were ordered to provide in advance of the Track 1A trial. The Court's Order thus raises no new issues. Moreover, while pharmacies themselves have suffered data breaches resulting in disclosure of HIPAA-protected information,[3] plaintiffs are unaware of any parallel breach in litigation under a protective order like the one the Court enacted here.

Second, the Pharmacy Defendants contend there is "no need whatsoever for data outside" the Track One bellwether counties (*i.e.*, Cuyahoga and Summit). This ignores plaintiffs' allegations concerning the migration of opioids, which are substantiated by considerable evidence obtained in Track 1A discovery. By way of example, high sales of oxycodone in Florida were tracked to illicit distribution in Ohio.[4] As such, the relevant discovery for the Track 1B trial necessarily includes data outside Cuyahoga and Summit counties.

This also ignores that these cases are part of an exceedingly complex and consequential MDL, in which thousands of counties and cities are making the same types of claims against the same Defendants. The order at issue centralizes national pharmacy discovery in the MDL Court, just as Track 1A did for the distributor and manufacturer cases (for example, with the production of

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[3] For example, a website called Healthcare IT Security states: "In 2018, the healthcare sector saw 15 million patient records compromised in 503 breaches." Jessica Davis, *The 10 Biggest Healthcare Data Breaches of 2019, So Far*, Health IT Security (July 23, 2019), https://healthitsecurity.com/news/the-10-biggest-healthcare-data-breaches-of-2019-so-far.

[4] *See, e.g.*, US-DEA-00000001 at 00000003 (DEA memorandum: "[DEA] Chief Boockholdt mentioned that because of the amount of oxycodone prescriptions being written, Florida, specifically South Florida has more pending pharmacy applications than all other states combined. Statistics are now showing this problem is spreading north into Georgia, Tennessee, Kentucky, Ohio and West Virginia.").

nationwide ARCOS data). This discovery will enable remand of subsequent streamlined cases, and will fulfill core purposes of consolidation by the JPML: the centralization of processes to avoid duplicative discovery disputes and inconsistent pretrial rulings and the conservation of judicial resources.

Third, the Pharmacy Defendants contend that the scope of production is too burdensome. The Court correctly found, however, that any burden is outweighed by the highly probative value of this information. As the Court has noted numerous times, this is not only perhaps the most complex civil litigation ever undertaken in the U.S., it also concerns a crisis of unmatched proportions that is ***ongoing***. To cite but one statistic, drug overdoses recently killed more people in just one year (2017) than Americans were killed in the Vietnam and Iraq Wars combined.[5] More than two-thirds of those deaths are opioid-related.[6] As such, it is unavoidable and not dispositive that discovery into the role pharmacies played in the crisis by failing to meet the Controlled Substances Act's suspicious order monitoring requirements would be expansive.

The Pharmacy Defendants' suggestion that plaintiffs first seek the information from the Ohio Automated Rx Reporting System ("OARRS") also is flawed. Among other limitations, OARRS only started collecting voluntarily-provided data in 2006[7]; the data was not mandatory until years later. And, as of 2013, only approximately 80% of pharmacists had entered prescriptions into the system.[8] The OARRS data collection is insufficient.

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[5] German Lopez, *It's Overdose Awareness Day – and overdoses are killing more Americans than ever before*, Vox (Aug. 31, 2018), https://www.vox.com/science-and-health/2018/8/31/17805226/opioid-epidemic-death-international-overdose-awareness-day.

[6] *Id.*

[7] https://www.ohiopmp.gov/About.aspx.

[8] https://www.dispatch.com/article/20131010/NEWS/310109616.

The Pharmacy Defendants were parties when the Court made these prior rulings. Some of the Pharmacy Defendants (or their parent companies) were also named as Distributor Defendants and were part of the Track 1A discovery and trial preparations. Notably, the Pharmacy Defendants do not substantively discuss these prior rulings – which are directly on point here – nor do they propose any modifications to those rulings, including to CMO 2, to ameliorate their purported concerns. Instead, they address the December 10, 2019 order, as if it arose in a vacuum rather than conforming to the prior rulings in this consolidated action. The Pharmacy Defendants identify no intervening changes in the law, no new facts, no limitation on their ability to present their defenses, and no violation of any due process rights.

The Court has strived to ensure that privacy interests of the parties and others are protected in this action. The Court also has made clear that, as a rule, nationwide evidence from 1996 to the present is at issue. The Pharmacy Defendants provide no reason for the Court to reconsider its December 10, 2019 Order or the prior orders on which it is based, and the motion should be denied.

BACKGROUND

On March 6, 2018, the Court entered the first protective order in this action, "Protective Order re: DEA's ARCOS/DADS Database." ECF No. 167. On April 11, 2018 the Court ordered the DEA to begin production of ARCOS data from the "States of Ohio, West Virginia, Illinois, Alabama, Michigan, and Florida." ECF No. 233 at 22. Although plaintiffs initially sought ARCOS data from January 1, 1995 to the present, they later modified the request to start on January 1, 2006 because "the ARCOS database includes data only from 2006 to the present," and earlier data "simply does not exist." *Id*. at 14. On June 26, 2018, the Court expanded the scope of DEA production of ARCOS data to include a wider range of opioid products and expanded the geographic range to the entire United States. ECF No. 668 at 2.

On May 15, 2018 the Court entered CMO 2, a second, more general protective order governing "all actions" consolidated in the MDL. ECF No. 441 at 6. Among other things, CMO 2 included a section titled "HIPAA-Protected Information," providing special protections for "Protected Health Information," as defined by 45 C.F.R. §160.103. *Id*. at 32. The Court found that "disclosure of such Protected Health Information is necessary for the conduct of proceedings before it and that failure to make the disclosure would be contrary to public interest or to the detriment of one or more parties to the proceedings." *Id*. at 33. Thus, the Court ***has already specifically authorized*** the disclosure of Protected Health Information pertaining to the action. *Id.* At the same time, recognizing the sensitive nature of Protected Health Information and the need for "special protection from public disclosure," the Court ordered any party that produces such information to designate it "Confidential Protected Health Information," subject to CMO 2's provision of heightened protection for such data. *Id.* at 32-33.

On July 17, 2018, Special Master Cohen entered Discovery Ruling No. 3, which ordered the Distributor Defendants to produce "transactional data and Suspicious Order Reports" starting from "January 1, 1996." ECF No. 762 at 4. Explaining the need for this evidence, the order found that "data showing opioid prescriptions and distributions began to increase dramatically in 1995, which is when Purdue launched Oxycontin" so if "plaintiffs, the Court, and a fact-finder are only allowed to see [data] beginning in 2006 [. . .], then the important beginning of the story is completely missing." *Id*. at 5-6. At that time, some of the Pharmacy Defendants sought separate rulings for their own data, but the Special Master rejected such requests, "declin[ing] to impose different discovery obligations on the pharmacy defendants than on the other distributor defendants." *Id.* at 8. Also in Discovery Ruling No. 3, Special Master Cohen limited the scope of transactional data to be produced at that time to "only Cuyahoga and Summit Counties," which was part of "a much-sharper focus on pursuing only the discovery that is absolutely necessary and appropriate for the bellwether trial

cases." *Id*. at 3-4. At that time, the first bellwether trials were set for just ten months from the date of the ruling (*i.e.*, March 2019).

On October 23, 2018, Special Master Cohen ordered the Pharmacy Defendants to produce "[d]ispensing-related documents contained in suspicious order monitoring files related to Track One jurisdictions." ECF No. 1055 at 5. While plaintiffs had sought comprehensive dispensing data, Special Master Cohen found that such data was not appropriate "at this time." *Id*. He also ruled, however, that the Pharmacy Defendants had "an obligation to ***preserve***" the comprehensive data because it would be relevant at "some future juncture." *Id*. (emphasis in original). That future juncture is now.

At the November 7, 2019 hearing, the Court noted that the immense work undertaken in Track 1A had led to a "one-off settlement," and concluded that "[t]his model isn't sustainable" since he'd have to live as long as Methuselah, conducting a trial a year for a thousand years, to begin to move towards global resolution. ECF No. 2913 at 3. As such, the Court stated that it would seek to remand cases to transferee judges, but found "it would be very unfair of me to ask any other judge in the country to go through what I've gone through over the past year." *Id.* at 13.

Counsel for one Defendant stated that, "[i]f there are a handful of cases spread out among a handful of judges, I actually don't think it will be unwieldy for those courts and those judges to deal with those particular issues," including overseeing "general discovery." *Id.* at 12, 14. The Court rejected this proposal to offload discovery issues to transferor courts out of hand, reminding counsel that the case had been "unworkable, unmanageable." *Id*. Yet that is precisely what the Pharmacy Defendants now seek. The Court's December 10, 2019 Order requiring production of national dispensing data, rolled out in stages, is the most efficient method of ensuring that this case proceeds in a timely manner toward resolution on a national scale.

STANDARD

"District courts have authority both under common law and Rule 54(b) to reconsider interlocutory orders and to reopen any part of a case before entry of final judgment." *Rodriguez v. Tenn. Laborers Health & Welfare Fund*, 89 F. App'x 949, 959 (6th Cir. 2004). However, "[m]otions for reconsideration are disfavored, and a motion for reconsideration is unfounded," *Davie v. Mitchell*, 291 F. Supp. 2d 573, 634 (N.D. Ohio 2003), unless there is "(1) an intervening change of controlling law; (2) new evidence available; or (3) a need to correct a clear error or prevent manifest injustice." *Luna v. Bell*, 887 F.3d 290, 297 (6th Cir. 2018) (quoting *Rodriguez*, 89 F. App'x at 959). None of these exceptions is present here.

ARGUMENT

I. The Agreed Protective Order (CMO 2) and Other Orders Already Provide the Safeguards the Pharmacy Defendants Seek

The Pharmacy Defendants claim the Court's December 10, 2019 order violates their customers' rights under HIPAA and the Fourth Amendment and demand the Court rescind most of it. Defs' Br. at 9-12. Yet the parties and the Court ***already addressed*** such concerns in the comprehensive protective order (CMO 2) more than 18 months ago. The Pharmacy Defendants simply assert that CMO 2 "can only reduce but not eliminate" the risk of disclosure, either because the Court will order the release of the data, or one of the parties will release it via an "unauthorized data breach." Defs' Br. at 12. The Pharmacy Defendants, however, never explain why they feel CMO 2 lacks adequate protection, what language or procedures could remedy their newly-discovered concerns about the potential release of confidential data, or why they ***agreed to*** the language 18 months ago if it was inadequate.

This very type of sensitive data has been produced by plaintiffs in this action, despite their objection, at the urging of Defendants. As counsel representing the interests of all Defendants (Donna Welch) stated in April 2019 regarding Defendants' purported need for CT1 medical claims

data, "***we know it's relevant, we know it's discoverable, and multiple protective orders have been entered*** . . . to protect medical claims data." 4/24/2019 transcript, 96:11-1. The same holds true for dispensing data now, and the Pharmacy Defendants provide no viable rationale for a different result.

A. All Parties and the Court Agree that HIPAA Concerns Have Been Properly Addressed

CMO 2 dedicates three full pages to HIPAA- and state law privacy-protections. *See* ECF No. 441. In it, the Court both finds "that disclosure of [] Protected Health Information is necessary for the conduct of proceedings before it and that failure to make the disclosure would be contrary to public interest or to the detriment of one or more parties to the proceedings," *id*. at 33, ¶74, and recognizes that Protected Health Information, as defined by HIPAA and state law, warrants "special protection from public disclosure and from any purpose other than prosecuting this Action," *id.* at 32, ¶70. In light of the need for both production and protection, the Court outlined specific steps that producing and receiving parties must take to designate discoverable material as "Confidential Protected Health Information" – including when, where, and how the designation must be made. *Id.* at 32-33, ¶¶72-73. The Court also restricted the classes of people who would have access to designated information, for what purpose, and for how long. *Id.* at 34, ¶¶75-76.

The Pharmacy Defendants recite their current concerns about protecting "Protected Health Information" (Defs' Br. at 9-10) but never explain why CMO 2 (which they agreed to) and the additional measures and restrictions adopted by the parties in CT1A and CT2 are insufficient. Plaintiffs agree that care must be taken to protect sensitive personal health information, including an individual's prescription records, under HIPAA and state privacy laws. That is why they agreed to CMO 2. Prior Court orders have compelled plaintiffs to produce such documents at defendants' demand. Plaintiffs raised privacy concerns when Defendants sought prescription-level claims data in CT1, including data points Pharmacy Defendants now are challenging. *See* 4/24/2019 transcript with Special Master Cohen, 97:17-24 (D. Ackerman stated that enhanced privacy protection

measures need to apply equally to CT1 Plaintiffs' medical claims data). CT2 Plaintiffs asserted the point again when Defendants sought documents containing HIPAA-protected information. *See* 11/26/2019 transcript with Special Master Cohen, 11:1-12:2 (P. Farrell raised the issue of how to safeguard HIPAA-protected data in plaintiffs' productions without impeding efficiency of litigation). In fact, plaintiffs repeatedly asserted this point throughout discovery, for example when Defendants sought insurance claims data from plaintiffs, and where appropriate, the Court entered additional orders covering these issues. *See, e.g.*, Order Governing Production of Medical and Pharmacy Claims Data in Track One Cases, March 7, 2019 (ECF No. 1421 at 4) (requiring notice to all other parties "[i]n the event that any Party learns of the unauthorized disclosure of Claims Data subject to this Order" and providing other protections).

Special Master Cohen, too, has recognized the need for care with production of protected health information. In considering whether Defendants were entitled to all claims data for CT1, beyond Summit and Cuyahoga's own claims data, he expressed concern about the potentially invasive impact of such a production:

> I think a lot of people out there would really care that you have data that shows that they got an opioid prescription and the diagnosis they got it for. There's a tremendous amount of private information.
>
> I get that we have protective orders, I understand that, but it's still a tremendous amount of private information that is HIPAA protected.

4/24/2019 transcript, 95:2-8.

Ultimately, the Special Master ordered the information to be produced, subject to the protective order and, where necessary, additional restrictions. *See* Order Governing Production of Non-Party OptumRx, Inc.'s Pharmacy Claims Data for Track One Cases (ECF No. 1635) (ordering production of claims data pursuant to the protective order and ECF No. 1421) and Order Governing Production of Non-Party Humana Health Plan of Ohio, Inc.'s Medical and Pharmacy Claims Data for Track One Cases (ECF No. 1641) (same).

In fact, this Court has addressed procedural safeguards in connection with the disclosure of HIPAA-protected prescription data and medical information, including CT1 Plaintiffs' data that Pharmacy Defendants surely intend to use in their defense, numerous times throughout this litigation – a point Pharmacy Defendants inexplicably ignore.[9] Consistently, when a party has raised HIPAA as a concern or defense to production, the Court or Special Master Cohen has pointed to the protective order already in place. *See, e.g.*, Track One Discovery Order Regarding Health-Related Information (ECF No. 703) at 1 (ordering CT1 Plaintiffs to produce de-identified HIPAA-protected prescription information where "[t]he Court has already entered an order addressing discovery of 'HIPAA-Protected Information,' *see* CMO-2 at 32-34 (docket no. 441), and the parties state they intend to abide by those provisions") and Discovery Ruling No. 7 (ECF No. 1051) at 3 (ordering CT1 Plaintiffs to produce opioid prescription claims data and medical data on an "Identified Basis," including "the name, address, social security number, and date of birth of the recipients of the prescriptions," and again noting: "All parties shall safeguard and maintain the confidentiality of this data pursuant to the terms of the HIPAA protective order").

The Court and Special Master also have addressed specific concerns when parties have raised them through agreed orders like the one entered in CT2 earlier this month, in which all parties ***except Pharmacy Defendants*** agreed to limitations. *See* Protective Order regarding Disclosure by Plaintiffs of Confidential Medical Records, applicable to Track Two Cases (ECF No. 2987); *see also* Nov. 21, 2018 Order (ECF No. 1147) (modifying Discovery Ruling No. 7) and Order Governing Production of Medical and Pharmacy Claims Data in Track One Cases (ECF No. 1421). Absent an order compelling production, the Pharmacy Defendants will be able to selectively use this information in

[9] Absent an order requiring Pharmacy Defendants' production now, Pharmacy Defendants will be able to use this very same information to identify pharmacists, prescribers and patients to depose, for example, while Plaintiffs will have their hands tied.

defense while Plaintiffs have no access to surrounding information. The Court should not permit this one-sided use of clearly relevant information.

B. Defendants' Claim that the Order Violates the Fourth Amendment Ignores Basic Constitutional Principles and Is Unsupported by Precedent

The Pharmacy Defendants claim the December 10, 2019 Order "authorizes an unreasonable – and likely unconstitutional – search" of patients' medical records. Defs' Br. at 10-12. First, they have no standing to assert a constitutional right on behalf of other persons. *See, e.g.*, *Rakas v. Illinois*, 439 U.S. 128, 139 (1978) (holding "the issue of standing involves two inquiries: first, whether the proponent of a particular legal right has alleged injury in fact, and, second, whether the proponent is asserting his own legal rights and interests rather than basing his claim for relief upon the rights of third parties"). Second, the Court has already conducted the requisite balancing test and determined that the need for nationwide dispensing information is compelling. Third, as noted above, Pharmacy Defendants' concerns are moot because the Court has fashioned comprehensive safeguards to protect patients' privacy.

First, Defendants here attempt to resist production by asserting ***patients'*** Fourth Amendment right to privacy – as opposed to their own. *See* Defs' Br. at 11. But the cases the Pharmacy Defendants cite address a person's standing to assert his or her own constitutional protections. In *Smith v. Maryland*, 442 U.S. 735 (1979), the plaintiff asserted an expectation of privacy in his ***own*** dialing activities. And in *Carpenter v. United States*, ___ U.S. ___, 138 S. Ct. 2206 (2018), a criminal defendant challenged the government's seizure of cell phone records tracking his historical geographic movements. *See also Riley v. California*, 573 U.S. 373 (2014) (criminal defendant challenging warrantless search of his cell phone); *Douglas v. Dobbs*, 419 F.3d 1097 (10th Cir. 2005) (plaintiff challenged district attorney's conduct in securing warrant for search and seizure of her own

prescription drug records). Here, Defendants attempt to assert privacy rights on behalf of third parties.

Second, Defendants' own authority suggests that even where a constitutional right is implicated (and it's not clear that any rights are implicated here), that privacy interest must be balanced against 'the public's interest in and need for the invasion of privacy.'" *Kallstrom v. City of Columbus*, 136 F.3d 1055, 1061 (6th Cir. 1998); *see also Turk v. Oiler*, 732 F. Supp. 2d 758, 770 (N.D. Ohio 2010) ("Under [HIPAA], a hospital's release of medical records to law enforcement ***is*** permitted under certain circumstances. Indeed, HIPAA specifically authorizes a hospital to release a patient's medical records in response to a grand jury subpoena.").[10] The Court has already conducted this balancing test several times in the past, as discussed above, and it has done so again here. Indeed, during the December 4, 2019 CT1B case management conference and in a subsequent proceeding with Special Master Cohen, Pharmacy Defendants and CT1 Plaintiffs discussed the scope of dispensing data to be produced. The Court considered the parties' discussion and then issued its order – balancing the public's interest in and need and patients' right to privacy. The Pharmacy Defendants proffer no explanation for where the Court supposedly erred.

Third, Pharmacy Defendants' admonitions about the Fourth Amendment right to privacy are moot in the context of CMO 2 and the many other safeguards that have been agreed to, ordered, and employed throughout this action. As discussed above, those safeguards have sufficiently protected ARCOS and HIPAA-protected data thus far, even for non-anonymized data.

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[10] The Supreme Court in *Plumhoff v. Rickard*, 572 U.S. 765, 778 (2014), held that "[o]ur cases make it clear that 'Fourth Amendment rights are personal rights which . . . may not be vicariously asserted.'" (citing *Alderman v. United States*, 394 U.S. 165, 174 (1969); *Rakas v. Illinois*, 439 U.S. 128, 138-43 (1978)). But that case involved the use of excessive force by the police. Also, in *DEA v. Utah Dept. of Commerce*, No. 2:16-cv-611-DN-DBP, 2017 WL 3189868, at *9 (C.D. Utah July 27, 2017), the Utah District Court held that a subpoena of prescription records was "a valid exercise of national power because it does not offend the Fourth Amendment. Physicians and patients do not have a reasonable expectation of privacy in the highly regulated prescription drug industry . . . ."

Defendants' argument is invalid on its face, as they may not assert Fourth Amendment privileges on behalf of patients. Defendants' own case law refutes their claim, and the Court has balanced privacy rights and instituted all appropriate and necessary safeguards. As such, the Court should reject Defendants' unavailing argument that the discovery order implicates Fourth Amendment concerns.

C. The Protective Order Provides Safeguards Adequate to Address 45 C.F.R. §164.306 Concerns

Defendants next argue that production of such data will lead to the Court ordering release of the confidential information or to "an unauthorized data breach" and that plaintiffs "are not subject to the same stringent requirements to safeguard data privacy and security." Defs' Br. at 12-13 (citing 45 C.F.R. §164.306). This is incorrect.

Defendants state that 45 C.F.R. §164.306 "tightly regulates how protected health information may be electronically stored and transmitted," suggesting that the protective order allegedly lacks such safeguards. Defs' Br. at 12. Yet a comparison of the regulation to the Court's protective order shows that they provide similar protections.

The regulation generally provides that entities handling confidential health information must:

> (1) Ensure the confidentiality, integrity, and availability of all electronic protected health information the covered entity or business associate creates, receives, maintains, or transmits.
>
> (2) Protect against any reasonably anticipated threats or hazards to the security or integrity of such information.
>
> (3) Protect against any reasonably anticipated uses or disclosures of such information that are not permitted or required under subpart E of this part.
>
> (4) Ensure compliance with this subpart by its workforce.

45 C.F.R. §164.306. The protective order similarly provides that "Protected Health Information" is entitled to "special protection from public disclosure and from any purpose other than prosecuting this Action." ECF No. 441 at 32. It prohibits the use or disclosure of "Protected Health Information

for any purpose other than the Litigation" and limits disclosure to counsel and their employees responsible for this litigation, the Court and its personnel (including court reporters), experts and consultants in this litigation, and other entities and persons involved in the litigation. *Id*. at 34. It requires that all Protected Health Information be destroyed or returned within 60 days of dismissal or entry of final judgment. *Id*. And it repeatedly references the Court's inherent authority to investigate and enforce the protective order. *E.g.*, *id*. at Exhibit A. Defendants have failed to identify any gaps in the protective order that would have prevented the parties from disclosing health information in the Counties' custody or control, or receiving the same information from insurers and other third party data sources, or that bar similar disclosures here.

Further, despite the large amounts of sensitive information produced in this litigation thus far, there have been no inadvertent disclosures. For instance, until the Court ordered unsealing of the national ARCOS data, the parties and their data providers successfully protected that data – in spite of incredible public interest in the data. Pharmacy Defendants' professed concerns about a possible data breach are nothing more than manufactured obstacles.

II. The Geographic and Temporal Scope of the December 10, 2019 Order Is Appropriate

The Pharmacy Defendants' arguments concerning the scope of the Order ignore both the history and magnitude of this litigation. They contend that the scope of the December 10, 2019 Order is "based on a misunderstanding," yet the only misunderstanding appears to be on the part of the Pharmacy Defendants. From the outset, the Court has been committed to providing meaningful solutions for abatement of the opioid epidemic devastating this country. The MDL since has grown to include more than 2,500 cases brought by cities, counties, Native American tribes and other plaintiffs across the country. Given the life-or-death stakes of this litigation for the plaintiffs and communities impacted by the opioid epidemic, the Pharmacy Defendants' claim of an undue burden in producing information on the drugs they sent into these communities rings hollow.

At the November 19, 2019 status conference, the Court made clear its intention to oversee general discovery in the MDL. *Id*. at 12, 14. In furtherance of that goal, the Court ruled on December 10, 2019 that "in keeping with the normal role of an MDL court overseeing centralized discovery in a case of national reach," the scope of discovery should extend backwards to 1996 and be national in scope. ECF No. 2976 at 2. In so doing, the Court cited Discovery Ruling No. 8. ECF No. 2976 at 2 n.1. In that ruling, Special Master Cohen warned the parties that although he was limiting the scope of dispensing data discovery (at a time when trial was just ten months away), the benefit/burden analysis under Rule 26(b)(1) would later be revisited, such as after the first trial. ECF No. 1055 at 5. That time has now arrived.

A. The Court Has Previously Made Clear that Broader Geographic Data Production Is Going to Be Required

The Pharmacy Defendants argue that the data they have been ordered to produce is irrelevant because "[p]laintiffs are challenging the filling of prescriptions in Cuyahoga and Summit Counties – not in Anchorage or Tulsa or Miami." Defs' Br. at 14. They also contend that "[t]hese Track One suits concern just two counties in Ohio." Defs' Br. at 18. These arguments are based on the same faulty logic as they were the last time the Pharmacy Defendants trotted them out in objecting to Discovery Rulings No. 2 and No. 3. ECF No. 785 at 9-11. In fact, as plaintiffs have repeatedly made clear, including in their Opposition to the Pharmacy Defendants' Objections to Discovery Rulings 2 and 3, the Pharmacy Defendants' distribution activities and practices outside of Summit and Cuyahoga counties are at issue: diversion elsewhere directly contributed to the flow of opioids into plaintiffs' counties. Moreover, the Pharmacy Defendants' knowledge of and response to diversion elsewhere in the U.S. bears on their knowledge of and culpability for the harms caused by their distribution activities within Cuyahoga and Summit Counties. *See, e.g.*, ECF No. 813 at 19-21.

The Pharmacy Defendants chalk the December 10, 2019 Order up to a "misunderstanding" by the Court. Defs' Br. at 18-19. They concede that the ARCOS data was national in scope, but

conclude that surely the Court must be confused because the distribution data was limited to Summit and Cuyahoga counties. Defs' Br. at 18-19. In fact, the prior geographic limitation on distribution data was imposed as part of "a much-sharper focus on pursuing only the discovery that is absolutely necessary and appropriate for the bellwether trial cases," which, at that point, were set for just ten months from the date of the ruling. Discovery Ruling No. 3, ECF No. 762 at 3 n.1, 4. And in a later discovery ruling when Special Master Cohen declined to allow more comprehensive dispensing-related data, he issued the following caveat:

> At some future juncture (e.g. after the first trial), the balance the Court must weigh under Fed. R. Civ. P. Rule 26(b)(1) may well shift, making plaintiffs' additional requested discovery appropriate. Accordingly, the Special Master makes clear here that defendants have no present obligation to produce the additional requested discovery, but they do have an obligation to preserve it.

ECF No. 1055 at 5. Since that time, as noted above, the Court has made clear that the prior model under which those orders were issued is unworkable and that the Court will not offload general discovery issues onto other judges. ECF No. 2913 at 12, 14.

The Pharmacy Defendants reject the notion that nationwide discovery is justified by the context of it occurring in an MDL, pointing to a single pharmacy defendant (Giant Eagle) that is not named in a case outside of Ohio. This argument, of course, does not apply to any other Pharmacy Defendant, and it also ignores Plaintiffs' evidence showing that opioids migrate.

The Pharmacy Defendants maintain that plaintiffs are not entitled to nationwide discovery because they have not filed a consolidated master complaint in the MDL. But they also agree that it is for good reason, as Plaintiffs have brought distinct claims in different states based on distinct legal theories. Defs' Br. at 21. They cite a footnote in *Gelboim v. Bank of Am. Corp.*, __ U.S. __, 135 S. Ct. 896 (2015), as support for their contention that filing a consolidated master complaint in the MDL is "a common procedure." Defs' Br. at 21 (citing *Gelboim*, 135 S. Ct. at 904 n.4). While footnote 4 is not on point, footnote 3 of the same opinion at least addresses this subject, but merely

states that parties "may elect to file a 'master complaint' and a corresponding 'consolidated answer,' which supersede prior individual pleadings." 135 S. Ct. at 904 n.3. The Pharmacy Defendants offer thus no basis whatsoever for their contention that a master complaint is a prerequisite for obtaining nationwide discovery.

The Pharmacy Defendants rely on a dissenting 7th Circuit opinion as support for their nonsensical argument that their due process rights are somehow violated because while Plaintiffs are allowed nationwide discovery, the Pharmacy Defendants will be allowed to take discovery "from two Ohio counties at best." Defs' Br. at 21 (citing *Swanson v. Citibank, N.A.*, 614 F.3d 400, 411 (7th Cir. 2010) (Posner, J. dissenting in part). It is unclear what nationwide data Summit and Cuyahoga counties possess, or how it could violate the Pharmacy Defendants' due process rights for Plaintiffs to provide data that doesn't exist. In *Swanson*, Judge Posner noted in dissent that defendants often want or need less discovery than do plaintiffs, and that such asymmetry may induce defendants to agree early in the litigation to a settlement favorable to a plaintiff. *See* 614 F.3d at 400. But plaintiffs, of course, cannot provide data that does not even exist just for the sake of creating some form of symmetry as to each defendant. Plaintiffs have incurred a tremendous discovery burden here, sitting for nearly 100 depositions and producing more than 20 million pages of documents. The Pharmacy Defendants cannot seriously claim to be the only burdened parties.

The Pharmacy Defendants offer up a series of reasons why having to produce nationwide discovery is overly burdensome, stating that discovery could be produced in as few as six weeks if limited to dispensing data in just Summit and Cuyahoga Counties, but that producing nationwide data would increase that time to a few or many months. Defs' Br. at 14, 19-20. And then they fret that they might even encounter "unforeseen obstacles," such that their estimates might be even further off. *Id*. at 20. But in its Order, the Court contemplates a rollout of discovery in a series of

phases: first Ohio data, then regional data, and then the rest of the country. ECF No. 2976 at 2. The Court also allowed for an all-at-once production in the event that proves less expensive.

The Court's nationwide discovery order is not based on a misunderstanding. The Court long has considered whether and when the benefits of nationwide discovery would outweigh its burdens, and correctly concluded that the litigation has developed to the point where it is appropriate.

B. The Temporal Scope Is Appropriate

The Pharmacy Defendants argue that since the DEA was only ordered to produce data going back to 2006, they should have the same start date. Defs' Br. at 15. This argument fails on examination of the entire record.

First, the DEA was only ordered to produce documents from its ARCOS database from 2006 forward because there were no pre-2006 records. As the Court noted in April 2018, the "Plaintiffs originally sought data beginning from January 1, 1995, which simply does not exist. Plaintiffs have since amended the 'begin-date' of their demand to January 1, 2006, so [plaintiffs' objection to the begin-date of data] is moot." ECF No. 233 at 14. Later, the Court expanded the scope of the DEA production to include more opioid products and "for the entire United States." ECF No. 668 at 2.

The Pharmacy Defendants should be held to the same standard as other Defendants, not the non-party DEA. The Distributor Defendants (many of whom are also Pharmacy Defendants) were ordered to produce transactional data going back to January 1, 1996. ECF No. 762 at 4. The Pharmacy Defendants contend, however, that there are "critical differences" between dispensing and distribution data that necessitate a more limited scope. Defs' Br. at 15. They then attach declarations attesting to the volume of dispensing data and the difficulty in protecting health data, which they contend would "require months of work by IT professionals." *Id.* at 16-17.

As noted above, however, the Court has made the benefit/burden calculation and determined that the burden on the Pharmacy Defendants is outweighed by the benefit of such data. Their

misguided assertion that plaintiffs "have made no showing as to why they would need this extraordinary amount of data" ignores the entire history of this case (and the role of the MDL Court, as noted above). Defs' Br. at 17. Plaintiffs allege the origin of the national opiate epidemic began with the launch of OxyContin in December 1995. In addition to OxyContin, hydrocodone consumption grew by more than 400% from 1995 to 2002. Since the mid-1990s, the volume of prescription opiates has continually risen along with abuse, addiction, morbidity and mortality. Limiting the temporal scope of dispensing data to 2006 would eliminate a critical timeframe in which opioid prescriptions expanded dramatically. Such data is crucial for providing a baseline, benchmark, and context, among other things.

In Discovery Ruling No. 3, Special Master Cohen credited plaintiffs' allegations, acknowledging the "'data showing opioid prescriptions and distributions began to increase dramatically in 1995, which is when Purdue launched Oxy[C]ontin'" and that "[i]f plaintiffs, the Court, and a fact-finder are only allowed to see . . . [data] beginning in 2006 . . . , then the important beginning of the story is completely missing." ECF No. 762 at 5-6. There is no reason for the Court to revisit this fact-based determination with respect to production of dispensing data.

C. The OARRS Data Is Incomplete and an Inadequate Substitute for Production from the Parties

The Pharmacy Defendants finally argue that plaintiffs and the Court should wait while they obtain a limited production from the Ohio State Board of Pharmacy, and then re-convene to see what else plaintiffs require. This cannot work.

First, if the pharmacies' real concern is "burden," they do not explain why the Court should shift any burden from the parties that allegedly caused the damage to a non-party public agency that has limited resources.

Second, the OARRS data simply does not address the scope of documents that plaintiffs request. The OARRS system is limited to Ohio. Further, OARRS data, just like the ARCOS data,

has existed only since 2006, and even then, the reporting of data was voluntary for years. The Court already has found that data predating 2006 is critical to the story. *See id.* Yet, Pharmacy Defendants posit that OARRS data is "far more complete" than Pharmacy Defendants' own data and that without the OARRS data, "it is impossible to get a meaningful picture of the marketplace." Defs' Br. at 22. To the contrary, the OARRS data represents but a fragment of the data at issue in the MDL, painting a picture of neither the relevant Ohio timeframe nor the nationwide reach of Pharmacy Defendants' activities. Moreover, Defendants' arguments fail to acknowledge the technical difficulty involved in using OARRS data, which, they may argue, does not accurately reflect their own data or knowledge (which includes interstate evidence of diversion and harms) and may not mesh with the data kept by other states' prescription drug monitoring programs to track red flags of diversion that would have been available in defendants' nationwide data systems.

For these reasons, OARRS not only does not contain the data plaintiffs requested, but also would create a baseless burden on the non-party state agency.

CONCLUSION

This Court has repeatedly worked to protect the privacy and confidentiality interest of the parties and individual patients. The Court also has made clear that nationwide discovery from 1996 to the present is relevant and now is appropriate to be produced. The Pharmacy Defendants provide no reason for the Court to reconsider its December 10, 2019 Order and the Court should deny their motion for reconsideration.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on December 24, 2019, the foregoing was filed electronically with the Clerk of Court using the Court's CM/ECF System, and will be served via the Court's CM/ECF filing system on all attorneys of record.

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